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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/134,333	08/14/1998	SHIRLEY LONGACRE-ANDRE	0660-0135-0X	7863

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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

GRUN, JAMES LESLIE

ART UNIT PAPER NUMBER

1641

DATE MAILED: 05/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/134,333	Applicant(s) LONGACRE-ANDRE ET AL.	
	Examiner James L. Grun	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 134, 139-143, 145 and 148-175 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 134, 139-143, 145 and 148-175 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

The amendment filed 24 February 2005 is acknowledged and has been entered. Claims 134, 139-143, 145, and 148-175 remain in the case.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 134, 139-143, 148, 150, and 166 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 134 and claims dependent thereupon, "the" atomic coordinates and "the" NMR fingerprints lack antecedent basis.

In claims 143, 150, and 166, it is not clear how being anchored to a parasite surface relates to anchoring to a eukaryotic cell membrane.

Applicant's arguments filed 24 February 2005 have been fully considered but they are not deemed to be persuasive for the reasons set forth above.

Claims 153, 156, 159, 162, 165, 169, 172, and 175 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Longacre (Mol. Biochem. Parasitol. 74: 105-111, 1995) in view of Longacre et al. (Mol. Biochem. Parasitol. 64:191, 1994) for reasons of record.

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Claims 134, 139-141, 143, 145, and 148-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Longacre in view of Longacre et al., and further in view of Holder et al. (U.S. Pat. No. 5,720,859) for reasons of record.

Applicant's arguments filed 24 February 2005 have been fully considered but they are not deemed to be persuasive.

Applicant urges that the combined teachings of the references do not suggest the use of a shorter sequence from amino acid residues 276-380, rather than the whole of residues 1-380, and that there is no motivation to combine the teachings of Longacre in view of Longacre et al., and further in view of Holder et al. These are not found persuasive for a number of reasons. Firstly, notwithstanding applicant's assertions to the contrary, the instant use of open claim language does not exclude a longer recombinant protein, as cloned in Longacre, that comprises the relevant fragment as instantly claimed. Secondly, the arguments are not found persuasive because the examiner recognizes that references cannot be arbitrarily combined and that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See: *In re Nomiya*, 184 USPQ 607 (CCPA 1975); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). However, there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. See: *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re McLaughlin*, 170 USPQ 209 (CCPA 1971). References

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are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. *In re Bozek*, 163 USPQ 545 (CCPA 1969). In this case, for the reasons of record, ample motivations have been set forth to clone and produce the C-terminal p42 and p19 fragments of MSP-1 proteins as notoriously old and well known vaccine candidates in the art as clearly taught by the references (see e.g. Longacre et al., page 192). As set forth, Holder et al. teach the incorporation of MSP-1 peptides comprising the EGF domains in vaccine compositions comprising alum.

Applicant urges that Longacre et al. teach N-terminal sequences of a length different from that as instantly claimed. This is not found persuasive in view of the instant disclosure at page 6 which describes the constructs of the reference as those of the invention and as claimed. Moreover, the reference of Longacre et al. clearly teaches that the constructs taught therein contain residues Met₁-Asp₃₂ (see e.g. Fig. 2).

Claims 151, 152, 154, 155, 157, 158, 160, 161, 163, 164, 166, 167, 168, 170, 171, 173, and 174 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of Chappel et al (Mol. Biochem. Parasitol. 60:303, 1993), Miller et al (Mol. Biochem. Parasitol. 59:1, 1993), Longacre et al (Mol. Biochem. Parasitol. 64:191, 1994), and Longacre (Mol. Biochem. Parasitol. 74: 105-111, 1995) for reasons of record. Although claim 152 is newly listed, its incorporation herein is not seen as a new ground of rejection as the prior rejection of this claim was implicit from the prior listing of all claims dependent thereupon.

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Claims 134, 139-143, 148, and 150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chappel et al., Miller et al., Longacre, and Longacre et al., and further in view of Holder et al. (U.S. Pat. No. 5,720,859) for reasons of record.

Applicant's arguments filed 24 February 2005 have been fully considered but they are not deemed to be persuasive.

In response to applicant's arguments that there are no specific suggestions to combine the references, the examiner recognizes that references cannot be arbitrarily combined and that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See: *In re Nomiya*, 184 USPQ 607 (CCPA 1975); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). However, there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. See: *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re McLaughlin*, 170 USPQ 209 (CCPA 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. *In re Bozek*, 163 USPQ 545 (CCPA 1969). In this case, for the reasons of record, ample motivations have been set forth to clone and produce the C-terminal p42 and p19 fragments of MSP-1 proteins comprising the conformational epitopes of the EGF-like domains as notoriously old and well known vaccine candidates in the art as clearly taught by the references (see e.g.: Chappel et al.; Longacre at al., page 192; Holder et al.). As set forth,

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Holder et al. teach the incorporation of MSP-1 peptides comprising the EGF domains in vaccine compositions comprising alum.

Notwithstanding applicant's assertions to the contrary, as notoriously old and well known in the art as taught in the references and as set forth in the rejections of record, one would have expected fragments of various lengths comprising the conformational epitopes of the EGF-like domains to function in a vaccine.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Holder et al. (U.S. Pat. No. 4,837,016) teach formulating vaccines containing MSP-1 proteins with alum as adjuvant (see e.g. col. 4).

Again, any of Murphy et al (Parasitology 100: 177-183, 1990), Chang et al. (J. Immunology 149: 548-555, 1992), Blackman et al. (FEMS Immunology and Medical Microbiology 6: 307-316, 1993), Egan et al. (Infection & Immunity 63(2): 456-466, Feb. 1995), Chang et al. (Infection & Immun. 64(1): 253-261, Jan., 1996), Shi et al. (Infection and Immunity 64(7): 2716-2723, July 1996), or Egan et al. (Infection and Immunity 65(8): 3024-3031, August 1997) teach recombinant proteins comprising the sequence of the p19 fragment of the *P. falciparum* MSP-1 protein capable of expressing native conformational epitopes.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


James L. Grun, Ph.D.
May 6, 2005


CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800-1641
5/9/05